



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Safety Data Sheet (MSDS)

According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards

Revision Date: 28 FEB 2026

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Zaleplon
- Product Number: ZAL-20260228
- Brand: SIGALD
- CAS-No.: 151386-49-3
- Synonyms: N-[3-(3-Cyanopyrazolo[1,5-a]pyrimidin-7-yl)phenyl]-N-ethylacetamide; Sonata

1.2 Supplier Details

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

1.3 Emergency Telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material for non-benzodiazepine hypnotic drug production (Z-drug class)
- Uses Advised Against: Direct human consumption; unauthorized pharmaceutical formulation; non-pharmaceutical use; veterinary use without official approval

SECTION 2: Hazards Identification

Summary of Emergency Measures	White crystalline powder. Harmful if swallowed; causes serious eye irritation; strong central nervous system depressant effects. Inhalation: Move to fresh air, rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, seek medical help. Swallowing: Rinse mouth, do not induce vomiting, call poison center immediately. Non-combustible; decomposes at high temp to release toxic cyanide fumes. No explosion risk.
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2.1 GHS Classification

- Acute toxicity, oral (Category 4); Eye irritation (Category 2); Specific target organ toxicity (single exposure), central nervous system (Category 2); Aquatic toxicity (Category 3)

2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
 - H302: Harmful if swallowed
 - H319: Causes serious eye irritation



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- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H335: May cause respiratory irritation; affects central nervous system
- H402: Harmful to aquatic organisms
- Precautionary Statements:
 - P261: Avoid breathing dust/fume/gas/mist/vapors/spray
 - P264: Wash hands thoroughly after handling
 - P270: Do not eat, drink or smoke when using
 - P280: Wear protective gloves/eye/face protection
 - P301+P312: If swallowed: Call a POISON CENTER/doctor if unwell
 - P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, continue rinsing
 - P342+P311: If experiencing respiratory symptoms: Call a doctor
 - P391: Collect spillage

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties; thermal decomposition at >250°C releases toxic cyanide and nitrogen oxide fumes

2.4 Health Hazards

- Acute: Severe drowsiness, dizziness, confusion (CNS depression); nausea/vomiting (swallowed); severe eye irritation; respiratory irritation/allergic reactions from dust inhalation

- Chronic: No known chronic toxic effects at occupational exposure levels

2.5 Environmental Hazards

- Harmful to aquatic organisms; low biodegradability; moderate bioaccumulation potential in aquatic food chains

2.6 Other Hazards

- Dust may cause allergic respiratory reactions in sensitive individuals

SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Zaleplon) | Component | CAS-No. | Concentration (w/w) | Classification | |---|---|---|---| | Zaleplon | 151386-49-3 | 100% | Acute oral toxicity Cat4; Eye irritation Cat2; CNS toxicity Cat2 | | Formula | C₁₇ H₁₅ N₅ O | - | Molecular Weight: 305.34 g/mol |

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- Inhaled: Move victim to fresh air, keep warm and at rest. Provide oxygen if breathing is difficult. **Seek immediate medical attention** if respiratory symptoms or CNS depression occur.
- Skin Contact: Remove contaminated clothing and rinse skin with running water for 10 minutes. Wash clothing before reuse; apply mild moisturizer if irritation occurs.
- Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes (hold eyelids open). Remove contact lenses if present. **Seek immediate medical attention** even if no irritation is felt initially.



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- Swallowed: Rinse mouth with water. Do not induce vomiting (risk of aspiration due to CNS depression). Call a poison center or doctor immediately and provide the product label.4.2 Most Important Symptoms
- Acute: Severe CNS depression (drowsiness, lethargy, confusion); eye redness/tearing/vision blur; nausea; allergic cough/shortness of breath (sensitive individuals)4.3 Medical Attention
- Symptomatic treatment required; airway management for CNS depression; flumazenil may be used for severe CNS depression (clinical guidelines only); no specific antidote for cyanide exposure (supportive care)4.4 Notes to Physician
- Inform the physician of zaleplon exposure; monitor CNS function, vital signs and respiratory status; be alert for allergic respiratory reactions

SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry powder (all suitable)5.2 Special Hazards from Combustion: Non-combustible; thermal decomposition at >250°C releases **toxic cyanide fumes, nitrogen oxides (NO_x)** and aromatic hydrocarbons5.3 Firefighter Advice: Wear self-contained breathing apparatus (SCBA) and full chemical protective gear; keep containers cool with water spray; avoid inhalation of decomposition fumes; prevent combustion products from entering water bodies

SECTION 6: Accidental Release Measures

- 6.1 Personal Precautions: Wear full PPE (nitrile gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from the spill area; avoid dust generation6.2 Environmental Precautions: Prevent spillage from entering drains, rivers or groundwater; collect all spilled material to avoid aquatic contamination; do not wash spill into water bodies6.3 Containment & Clean-Up
- Small Spill: Sweep up with an inert brush (no plastic) and transfer to a sealed HDPE container for professional hazardous waste disposal
 - Large Spill: Contain with plastic dikes; wet the spill to prevent dust generation; transfer to sealed drums with a clean shovel; clean the area with a small amount of DMSO and collect wash liquid for disposal6.4 Reference: See Section 13 for waste disposal guidelines

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate in a well-ventilated, dust-free GMP workshop; use closed, dust-free handling/transfer systems to avoid dust generation and inhalation
- Avoid contact with strong acids, strong bases, high temperature (>60°C) and open flame to prevent decomposition and toxic fume release
- Hygiene Measures: Wash hands and face thoroughly with soap and water after handling; no eating/drinking/smoking in the work area; conduct pre-employment and regular respiratory health checks for personnel7.2 Safe Storage

- Storage Conditions: Cool, dry, dark warehouse (2-8°C); keep container tightly sealed; protect from light and high temperature (>25°C)
- Incompatibilities: Strong acids (HCl/H₂SO₄), strong bases (NaOH/KOH), oxidizing agents, open flame, high temperature
- Storage Class (TRGS 510): 6.1 (Toxic Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Segregation: Store as a controlled pharmaceutical raw material; separate from food, feed, strong acids/bases and oxidizing agents; keep in a locked storage area with authorized personnel only

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 0.1 mg/m³ (respirable dust) (EU/China proposed)

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency HEPA dust collection; dust-free Class 10000 workbench (pharmaceutical grade); light-proof processing equipment
- Personal Protective Equipment (PPE):
 - Eye/Face: Chemical safety goggles + face shield (mandatory for all handling)
 - Skin: Nitrile rubber gloves (≥0.11 mm) + chemical-resistant lab coat + disposable arm covers + shoe covers
 - Respiratory: N95 dust mask (normal handling); powered air-purifying respirator (PAPR) for high-dust environments; SCBA for spill/fire scenarios
 - Hand: No bare hand contact; replace gloves immediately if damaged or contaminated
- Medical Surveillance: Pre-employment and annual respiratory health checks for all handling personnel

SECTION 9: Physical and Chemical Properties

- Physical State: White to pale yellow crystalline powder | Odor: Practically odorless
- Melting Point: 185-189°C | Boiling Point: Decomposes before boiling (>250°C)
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature: >400°C | Decomposition Temperature: ≥250°C (releases toxic fumes)
- pH Value: 6.0-8.0 (0.1% in DMSO, 25°C) | Water Solubility: Sparingly soluble (0.18 g/100 mL, 25°C)
- DMSO Solubility: Soluble (≥20 g/100 mL, 25°C) | Density (25°C): 1.32 g/cm³
- Vapor Pressure (25°C): <0.0001 hPa | Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: None | Oxidizing Properties: None
- Light Sensitivity: Sensitive (degrades under direct sunlight) | Hygroscopy: Slight

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions (2-8°C, dark, sealed); slight hygroscopy and light sensitivity with no significant chemical degradation

10.2 Hazardous Reactions: No hazardous reactions under normal use and handling; thermal decomposition at

>250°C releases toxic cyanide and nitrogen oxide fumes
10.3 Conditions to Avoid: Direct sunlight, high temperature (>60°C), high humidity (>60%), strong acids/bases, oxidizing agents, open flame
10.4 Incompatible Materials: Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, hydrogen peroxide (30%+), potassium permanganate
10.5 Hazardous Decomposition Products: Hydrogen cyanide (HCN), nitrogen oxides (NO_x), carbon monoxide (CO), aromatic hydrocarbons

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD₅₀) = 980 mg/kg; Dermal (Rabbit, LD₅₀) >2000 mg/kg; Inhalation (Rat, LC₅₀) >3 mg/m³ (4h)
- Skin Irritation: No irritation (Rabbit, 4h exposure)
- Eye Irritation: Category 2 (severe redness, tearing and corneal irritation, reversible in 72h; Rabbit, 24h exposure)
- Respiratory Sensitization: May cause allergic respiratory reactions in sensitive individuals (human and animal studies)
- Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans)
- Reproductive Toxicity: No reproductive harm at normal occupational exposure; high doses cause fetal developmental delays (animal studies)
- CNS Toxicity: Strong dose-dependent depressant effects (drowsiness, lethargy, confusion, coma at high doses); rapid onset and short duration of action (clinical characteristic)

SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish (LC₅₀) = 22 mg/L (96h); Daphnia (EC₅₀) = 15 mg/L (48h); Algae (EC₅₀) = 28 mg/L (72h)
12.2 Persistence & Degradability: Low biodegradability (BOD₅/COD <0.3) in aquatic environments; degrades within 60 days under aerobic conditions
12.3 Bioaccumulative Potential: Moderate (Log P = 2.8); may bioaccumulate in aquatic organisms and food chains
12.4 Mobility in Soil: Low (binds strongly to soil organic matter; no leaching to groundwater)
12.5 PBT/vPvB: Classified as P (Persistent) and B (Bioaccumulative); not vPvB
12.6 Other Adverse Effects: Inhibits aquatic organism feeding and reproductive behavior at high concentrations; long-term ecological risk at uncontrolled release levels

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- Product Waste: Classified as hazardous pharmaceutical waste with toxic decomposition products; incinerate at **licensed hazardous waste incineration facilities (≥1400°C)** with dedicated acid gas and cyanide treatment systems
 - Packaging Waste: Rinse packaging with a small amount of DMSO; collect rinsate for hazardous waste treatment; dispose of packaging as hazardous waste (no recycling)
- 13.2 Disposal Regulations: Comply with China HW02 (Medical Waste) and Basel Convention; strictly



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prohibit disposal with municipal solid waste or aquatic environments; follow local toxic waste disposal regulations

SECTION 14: Transport Information

14.1 UN Number: UN 2811 14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s.

(Zaleplon) 14.3 Transport Hazard Class: 6.1 (Toxic Substances) | Packaging Group: III 14.4

Environmental Hazards: Marine Pollutant (No) 14.5 Special Transport Precautions

- Transport in **2-8°C cold chain**; use light-proof, sealed HDPE/amber glass packaging; mark with GHS hazard labels + UN 2811 + controlled drug signs
- Avoid direct sunlight, high temperature, collision and vibration during transport; do not transport with food/feed/strong acids/bases/oxidizing agents/open flame
- Comply with IMDG/IATA/ADR regulations for Class 6.1 toxic solids (cold chain) and local controlled pharmaceutical raw material transport regulations

SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: NMPA Controlled Pharmaceutical Raw Material; Pharmacopoeia (2020); Hazardous Chemicals List (2015)
- EU: REACH Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC; Schedule IV controlled drug
- US: TSCA Listed; USP 45 compliant; FDA-regulated; DEA Schedule IV controlled substance 15.2
- Other: Comply with local pharmaceutical manufacturing, controlled drug management, GMP and hazardous waste disposal regulations

SECTION 16: Other Information

- This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9; based on current scientific and regulatory knowledge
- Supplier is not liable for damage caused by improper handling, storage, use or non-compliance with safety precautions
- For additional technical or regulatory information, contact the supplier's pharmaceutical technical department